

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

_____)	
BRECKENRIDGE PHARMACEUTICAL, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 07-CV-11114(RWS)
)	
MIDLAND HEALTHCARE, LLC,)	
)	JURY TRIAL DEMANDED
Defendant.)	
_____)	

LOCAL CIVIL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS

In support of its motion for summary judgment, Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") submits that the following are material facts concerning which there is no genuine issue to be tried:

1. On January 26, 2007, Breckenridge and Defendant Midland Healthcare, LLC ("Midland") entered into an ANDA Development, Manufacture, and Supply Agreement (the "Agreement"), relevant portions of which are filed herewith as Exhibit 1 to the declaration of Larry J. Lapila.¹ Lapila Decl., ¶ 2.

2. The Agreement provides that Breckenridge was to pay Midland a certain sum for development of a prescription product (the "Product") so Breckenridge could submit an Abbreviated New Drug Application ("ANDA") for approval by the United States Food and Drug Administration (the "FDA"), in order that the Product could be marketed in the United States.

¹ Because of the confidential nature of the Agreement, only the pertinent pages (redacted) are submitted herewith. If necessary, a full copy will be filed under seal at an appropriate time, upon approval of the requisite motion.

See Agreement (Exh. 1), at section 2.1 and Exhibit B thereto; Lapila Decl., ¶ 3.

3. The services to be rendered by Midland pursuant to the Agreement were those required for “the development of the Product for submission of an ANDA.” These “services” were further defined to include specific development steps: “formulation development, pilot-scale and scale-up batch manufacturing, analytical method development, method validation, and stability testing for the Product.” Agreement (Exh. 1), section 2.1(a) and (b).

4. In Exhibit B to the Agreement, these services were broken down into certain “milestones.” Exhibit B provides that certain specified payments were to be made by Breckenridge to Midland upon the achievement of these “milestones.” *Id.*, Exhibit B thereto.

5. The second milestone in the Agreement is the “completion of formulation development,” which was to be achieved 120 days after the execution of the Agreement. *Id.* The Agreement defines “completion of formulation development” to include “comparative assay results for the pilot-scale batch, and successful completion of analytical method validation, including impurities.” The Agreement (Exh. 1), section 1.7.

6. In addition, one of the standard steps required for formulation development of a pharmaceutical product is stability testing on product that has been produced pursuant to the formulation. Lapila Decl., ¶ 11.

7. By 280 days from commencement, Breckenridge was to receive the results from a completed three-month stability test. Agreement, Exhibit B. Accordingly, stability testing was to begin by approximately early August, 2007.

8. Midland advised Breckenridge that stability testing had been performed on a development batch of the Product, and that appropriate progress was being made on the subsequent milestones. Lapila Decl., ¶ 8.

9. In spite of its contractual obligation to provide accurate monthly status reports, Midland failed to advise Breckenridge that in fact the formulation development had not been completed. Lapila Decl., ¶ 8.

10. Based on Midland's representations, Breckenridge paid to Midland a total of \$200,000. Lapila Decl., ¶ 9.

11. In September, 2007, Mr. Larry Lapila, Vice President of Business Development for Breckenridge, along with regulatory consultant, Mr. Robert Falconer, conducted an on-site audit of Midland's progress. Lapila Decl., ¶ 12; Falconer Dec. ¶ 2.

12. They learned during this on-site visit that, contrary to Midland's earlier representations of progress, Midland had not produced a pilot-scale batch, had not produced comparative assay results, had not completed analytical method validation, and had not performed (or even begun to perform) stability testing of the formulation. Lapila Decl., ¶ 13; Falconer Dec. ¶ 4.

13. To this date, Midland has still not rendered any of the services required by section 2.1 of the Agreement, and none of the milestones specified in Exhibit B to the Agreement except for "Execution of Agreement." *See* Exhibit B to the Agreement (Exh. 1); Lapila Decl., ¶ 14.

14. Accordingly, under the terms of the Agreement, so long as it stayed in effect, Midland had a right to be paid only \$25,000. *Id.*

15. On September 26, 2007, Mr. Lapila emailed Mr. Raman ("Ray") Kapur of Midland that Breckenridge had learned from its site visit that stability testing had not been performed on a development batch as Midland had previously represented, and that the Product development was off schedule. Lapila Decl., ¶ 15; Exhibit 2 (09/26/2007 email to Midland).

16. Because Mr. Lapila had promoted this project with Midland to his colleagues in

Breckenridge, he subsequently emailed to Mr. Kapur, on November 12, 2007: “You have put me in a VERY embarrassing position. . . . This project has died due to Midland’s failure to get it up on stability in a timely manner. Since our visit I have found it impossible to get information from you.” Lapila Decl., ¶ 16; Exhibit 3 (11/12/2007 to 11/19/2007 emails between Midland and Breckenridge).

17. Mr. Lapila also asked for the return of the money paid by Breckenridge to Midland. Lapila Decl., ¶ 17; Exh. 3.

18. Mr. Kapur’s reply emails to Mr. Lapila do not contradict Mr. Lapila’s assertions that the project had “died due to Midland’s failure to get it up on stability in a timely manner,” nor did Mr. Kapur disagree with Mr. Lapila’s other assertions, but instead effectively admits them. *See* Exhibit 3.

19. Rather than disagree with Mr. Lapila, Mr. Kapur apologized twice for putting Mr. Lapila in this position, requested time to complete a “restructuring transaction,” and stated that he would come back to Breckenridge “with a proposal,” and was “looking into a couple of other things . . . to see what else we can do together.” Exh. 3.

20. Midland also failed to provide to Breckenridge at least two consecutive monthly reports that were required by the section 2.3 of the Agreement, and failed to provide other reports requested by Breckenridge as well. *See* Agreement (Exh. 1), at section 2.3; Lapila Decl., ¶ 20.

21. According to the terms of the Agreement, because Midland did not accomplish any of the milestones or render any of the services provided for in the Agreement (other than the execution of the Agreement itself), Midland would have been paid only \$25,000 by Breckenridge but for Midland’s misrepresentation of the progress that had been made in the development of the Product. *See* Exhibit B to the Agreement (Exh. 1).

22. Midland has not returned any of the money paid to it by Breckenridge for the development of the Product. Lapila Decl., ¶ 17.

23. In light of Midland's failures to achieve the milestones and to provide the requisite reports, on November 30, 2007, Breckenridge sent to Midland a letter terminating the Agreement pursuant to section 7.2 of the Agreement. Lapila Decl., ¶ 22; Exhibit 4.

24. Thus, by its terms, the Agreement was terminated effective Tuesday, January 29, 2008. *See* Agreement (Exh. 1), section 7.2.

25. Because Midland has not rendered any of the services to be provided to Breckenridge pursuant to section 2.1 of the Agreement or Exhibit B thereto, Midland has not performed any "actual services rendered" for which it would have a right to be paid pursuant to the final paragraph section 7.2(b) of the Agreement. *Id.*; Lapila Decl., ¶ 23.

26. Accordingly, upon termination of the Agreement Midland is obligated to return to Breckenridge not only the \$175,000 wrongly paid to it while the Agreement was in effect, but also the \$25,000 paid to Midland upon execution of the Agreement.

Dated: New York, New York
January 30, 2008

/s/ C. Randolph Ross
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